

Appln. No. 10/056,831
Amdt. dated December 8, 2004
Reply to Office action of Sept. 9, 2004

REMARKS

Claims 1-17 are pending in the application. By this Amendment, claims 1, 7 and 13 are amended. The amendments do not introduce new matter as they are fully supported in the specification. For example, support for the amendments of claims 1, 7 and 13 may be found in the specification on page 4, lines 12-15, page 8, lines 12-21, and in FIG. 3. Applicant respectfully requests reconsideration and allowance of all claims in view of the above amendments and following remarks.

Claims 1-17 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Nos. 5,389,080 and 5,441,486 to Yoon, U.S. Patent No. 5,360,417 to Gravener et al., and further in view of U.S. Patent No. 5,634,911 to Hermann et al. Applicant respectfully traverses this rejection because none of the cited prior art, either alone or in combination, discloses or suggests the claimed invention.

An embodiment of the claimed invention, as amended in claim 1, is directed to an access device in the form of a trocar having a cannula, a housing, and a valve including a gel material. The gel material is unique in having floating or off-axis movement properties relative to the axis to maintain a seal with a surgical instrument even when the surgical instrument is inserted or moved laterally from the axis. Stated another way, a feature of the invention is it allows off-axis insertion or movement of a surgical instrument without the loss of insufflation gas. See, for example, FIG. 3 and page 8, lines 12, to page 9, line 10, of the description, which explains that "the instrument 25 may be inserted along the axis 27, it may also be inserted off-axis or

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moved off-axis... Under these circumstances, it is important that the instrument seal 61 be maintained, or permitted to 'float' with the off-axis movement of the instrument 25... It is the properties of the gel material 54 which make it particularly desirable for floatation purposes." (Emphasis added.)

Neither of the Yoon reference nor Gravener discloses the above features of the invention. The Examiner admits to this on Page 3 of the Action stating that "[t]he cited patents do not expressly disclose gel having off[f] axis movement properties when an instrument is moved laterally from the axis of the trocar." The Examiner asserts, however, that Hermann discloses "a trocar stabilizer using gel having properties to allow for the lateral movement of the medical instrument inserted in the port." The Examiner specifically pointed out to FIG. 12a and noted how wide the various embodiments presented in this patent are as compared to a trocar tubular wall. The Examiner further noted that "the [Hermann] stabilizer is used to insert laparoscopic instruments that require the ability to be laterally moved while at the same time, maintaining a seal."

Applicant respectfully submits that the Hermann stabilizer does not disclose the instrument seal of the claimed invention. In fact, Hermann did just the exact opposite by specifically disavowing the teaching of a true instrument seal in column 7, lines 57-64, stating that "[a]s the graspers are manipulated, the membrane conforms around the graspers but yields to allow the graspers to be open, closed, twisted, pushed and pulled within the skin seal without substantially degrading the seal created by the membrane. It should be noted that a perfectly airtight seal is not necessary, and some leakage of insufflation gas or fluid is acceptable..." (Emphasis added.) "In construing claims, the

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analytical focus must begin and remain centered on the language of the claim themselves. The ordinary meaning must be determined from the standpoint of a person of ordinary skill in the relevant art... The ordinary and customary definition will be overcome if [the] inventor has disavowed or disclaimed scope of coverage [anywhere in the file history], by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Nystrom v. Trex Co.*, 71 USPQ2d 1241 (Fed. Cir. 2004) (citing *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 64 USPQ2d 1812 (Fed. Cir. 2002)). From at least Hermann's statement, applicant respectfully submits that one of ordinary skill in the art would not consider Hermann as an "obvious" design choice when considering a gel that permits lateral movement while maintaining a seal.

Referring to FIG. 12a, Hermann discloses a skin seal 10 having a lumen 14 and thin skin 46 that can be packed with any resilient foam material. Hermann went on to describe that the skin 46 may be replaced with a layer of plastic or elastic material while the packing may be made of a gel, gel-filled membrane or soft rubber. In any case, "[t]he packing is formed to fit into the skin seal[,] ... through which surgical instruments may be inserted into the body." (Emphasis added.) Column 8, line 66. In other words, the packing (gel) of Hermann does not "maintain [a] second seal with the surgical instrument" like the claimed invention. Instead, it is the skin seal (plastic or elastic layer) that provides the outer seal structure for the surgical instrument. Without the skin seal, there would be nothing to support the packing; that is, there is no indication or suggestion whatsoever that the Hermann gel alone could seal an instrument (especially

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after Hermann's disavowal statement). Furthermore, without the skin seal, there is also no indication or suggestion that the Hermann gel could allow off-axis movement (since Hermann does not disclose any gel properties). Accordingly, applicant respectfully submits that Hermann is directed to a different invention that is structurally and functionally different from the claimed invention and, therefore, it would not have been obvious to one skilled in the art at the time of the invention to combine any of the cited prior art to arrive at the claimed invention.

In sum, applicant respectfully requests withdrawal of the rejection of claims 1-17 under 35 U.S.C. §103(a), and that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



Kenneth K. Vu
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Date: December 8, 2004


PTO/SB/21 (02-04)


Approved for use through 07/31/2006. OMB 0651-0031

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/056,831	
	Filing Date	January 24, 2002	
	First Named Inventor	John R. Brustad	
	Art Unit	3763	
	Examiner Name	Manuel A. Mendez	
Total Number of Pages in This Submission	13	Attorney Docket Number	A-2207-AL

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input checked="" type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm or Individual name	KENNETH K. VU	
Signature		
Date	December 8, 2004	

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Signature		Date December 8, 2004

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Effective on 12/08/2004. Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). FEE TRANSMITTAL For FY 2005		Complete If Known		
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Application Number	10/056,831	
		Filing Date	January 24, 2002	
		First Named Inventor	John Brustad	
		Examiner Name	Manuel A. Mendez	
		Art Unit	3763	
TOTAL AMOUNT OF PAYMENT (\$)		0.00	Attorney Docket No.	P-2207-AL

METHOD OF PAYMENT (check all that apply)	
<input type="checkbox"/> Check <input type="checkbox"/> Credit Card <input type="checkbox"/> Money Order <input type="checkbox"/> None <input type="checkbox"/> Other (please identify): _____	
<input checked="" type="checkbox"/> Deposit Account Deposit Account Number: <u>01-2215</u> Deposit Account Name: <u>Applied Medical Resources Corporation</u>	
For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)	
<input checked="" type="checkbox"/> Charge fee(s) indicated below <input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee	
<input checked="" type="checkbox"/> Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 <input checked="" type="checkbox"/> Credit any overpayments	
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3. APPLICATION SIZE FEE																																																
If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).																																																
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SUBMITTED BY		
Signature	<u>Kenneth K. Vu</u>	Registration No. (Attorney/Agent) <u>46,323</u>
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		Date <u>December 8, 2004</u>

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